EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Joseph Meara on 2/10/09.

The application has been amended as follows:

Amend claim 1 to read:

1. (Currently amended) Sustained release tablet comprising ~~containing~~ 1.5 to 2.5% of total mass of the tablet of indapamide, 30 to 80% of total mass of the tablet of lactose monohydrate, 2 to 10% of total mass of the tablet of copovidone, 20 to 65% of total mass of the tablet of hypromellose, and 0.1 to 5 % of total mass of the tablet of lubricant, wherein the tablet is prepared by a method comprising mixing indapamide with lactose monohydrate and copovidone and then moisturizing the mixture with purified water and performing granulation after which the granulate is dried, cooled, mixed with hypromellose and lubricant and compressed in a tableting machine.

Amend claim 4 to read:

4. (Currently amended) Process of manufacturing sustained release tablet containing indapamide, comprising mixing indapamide with lactose monohydrate and copovidone and then moisturizing the mixture with purified water and performing granulation after which the

granulate is dried, cooled, mixed with hypromellose and lubricant and compressed in a tableting machine, wherein the tablet comprises 1.5 to 2.5% of total mass of the tablet of indapamide, 30 to 80% of total mass of the tablet of lactose monohydrate, 2 to 10% of total mass of the tablet of copovidone, 20 to 65% of total mass of the tablet of hypromellose, and 0.1 to 5 % of total mass of the tablet of lubricant.

The following is an examiner's statement of reasons for allowance: The prior art combination treats the povidone and copovidone as functional equivalents that are interchangeable. Applicant establishes, in comparative experiments documented in the Declaration dated 11/21/08 that, copovidone provides a superior particle size distribution for use in the instantly claimed formulation. Due to the high percentage of hypromellose in the formulation, the particle size of the granulate directly effects the homogeneity and thus the release of the indapamide. As such if the granulation of the indapamide, lactose and copovidone are similar in size to that of the hypromellose during processing the tablet with have increase homogeneity and a superior sustained release. When compared granulation comprising copovidone provided more favorable particles for combination with hypromellose. The smaller sizes of the copovidone granulation allows for improved homogenizing with hypromellose and therefor improved control over the sustained release of the indapamide. This result is surprising since the prior art establishes povidone and copovidone as functional equivalents that would presumably perform identically. For these reasons the claims are novel and non-obvious due to the showing of unexpected results with the use of copovidone in the specific formulations claimed and the process for their manufacture.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 7:00-4:30; every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618